

FEE

DP BARCODE No.: 373454

FILE SYMBOL No.: 87243-R

DECISION No.: 425434

PC Code(s): 106201

ACTION CODE: R 170

FOOD Use: No

NON-FOOD Use: Yes

DATE OUT: September 30, 2010

SUBJECT: End Use Product Chemistry Review
Product Name: Apivar Strips

FROM: Bruce F. Kitchens, Chemist
Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

Bruce F. Kitchens
30 Sept 2010
SIRM (096)10

TO: PM 07, John Hebert/Julie Chao
Insecticide-Rodenticide Branch / Registration Division (7505P)

Company Name: Veto-Pharma SA

Formulation Type: Solid

INTRODUCTION:

The applicant requested a new non food end use product. This product is intended for use as a miticide on honey bees.

In support of the application, the applicant submitted product chemistry data corresponding to guideline 830 series, group A & group B and contained in MRID#s 479427-01 and 479427-02. TRB has been asked to determine the acceptability of the product chemistry data and the proposed basic Confidential Statement of Formula (CSF) dated 22 Dec 2009.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient: Amitraz
2. The source material of the active ingredient is derived from a registered source.
3. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled uses.
4. Confidential Statement of Formula(s):

[X] Basic -

Date: 22 Dec 2009

Resubmitted (via e-mail): 30 Sept 2010

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5. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2)

☒ Yes, if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA;

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid equivalent: ☐ Yes ☒ NA; {name} acid equivalent = xx %

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☐ No ☒ NA

Methanol at > 4%: ☐ Yes ☐ No ☒ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Is the sub statement in compliance with PR Notice 97-6? ☐ Yes, if not, explain below:

- d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No; if yes explain below:

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7. Group A: Product Chemistry Data

TRB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		x		A	479427-01
830.1600	Description of materials used to produce the product		x		A	479427-01
830.1650	Description of formulation process		x		A	479427-01
830.1670	Discussion on the formation of impurities		x		A	479427-01
830.1700	Preliminary analysis **				N/A	479427-01
830.1750	Certified limits (158.350)	Standard certified limits	x			
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		x		A	479427-01

A = Acceptance, N = Not Acceptable, G = Data Gap,
W = Waiver Request, I = In Progress, NA = Not Applicable

** Group A and B product chemistry data are required for both the end use product and the active ingredient source.

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8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Solid	A	479427-02
830.6315	Flammability	Product does not contain flammable components	N/A	
830.6316	Explodability	Product dose not contain explosive components	N/A	
830.7000	pH	Product not dispersible with water	N/A	
830.7300	Density (units)	0.88 g/cm ³	A	479427-02

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NA = Not applicable, I = In progress

CONCLUSIONS:

TRB has reviewed the CSF(s) and product chemistry data for the proposed end use product and has concluded:

1. Basic CSF dated 22 Dec 2009 is acceptable and attached.
2. All required Group A data were reviewed and determined to be acceptable.
3. All required Group B data were reviewed and determined to be acceptable.
4. The proposed label was screened as it pertains to the product chemistry requirements. The final review of the proposed label and uses are the purview of the PM team.